UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DEBRA COONAN, **Plaintiff,** **v.** **ETHICON, INC., ETHICON LLC, and JOHNSON & JOHNSON,** **Defendants.**	**CIVIL ACTION NO. 4:21-10310-TSH**

ORDER AND MEMORANDUM ON DEFENDANTS' MOTION TO DISMISS (Docket No. 20

November 3, 2021

HILLMAN, D.J.

Plaintiff Debra Coonan brings this action against defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson for products liability claims related to the defendants' medical devices. Coonan alleges negligence (Count I), products liability - design defect (Count II), products liability - failure to warn (Count III), breach of express warranty (Count IV), breach of implied warranty (Count V), and discovery rule and fraudulent concealment (Count VI). The defendants move to dismiss Counts I, II, IV, and VI for failure to state a claim. *See* Fed. R. Civ. P. 12(b)(6). The Court ***grants*** the motion as to Counts I, II, and VI and ***denies*** the motion as to Count IV. Dismissal of Count II is without prejudice and with leave to amend. *See* Fed. R. Civ. P. 15(a)(2).

Background

The following facts, taken from the complaint, are accepted as true. *See Rosenberg v. City of Everett*, 328 F.3d 12, 15 (1st Cir. 2003). The defendants design, manufacture, and sell medical

devices. (Am. Compl. at ¶ 9). The defendants' Gynecare Prolift and Gynecare TVT Secur devices contain polypropylene mesh and, when implanted in a woman's pelvis, are meant to restore normal pelvic function. (*Id.*).

In 2007, Coonan was diagnosed with grade 3+ cystocele, and a doctor recommended that she undergo implantation of the TVT-Secur and Prolift devices to treat her condition. (*Id.* at ¶ 34). Coonan did so that year. (*Id.* at ¶ 35). In 2018, Coonan was required to undergo surgery to remove the TVT-Secur mesh, which had eroded into her bladder. (*Id.* at ¶ 36). In May 2019, she was required to undergo a second procedure to remove additional portions of the devices that had eroded into her vagina and bladder. (*Id.* at ¶ 37). In September 2019, Coonan underwent a third surgery to remove mesh that had again eroded into her bladder. (*Id.* at ¶ 38). She continues to feel pain from the devices and will require additional surgeries. (*Id.* at ¶ 39).

The devices were marketed to the medical community and patients as safe, effective, and reliable. (*Id.* at ¶ 12). The devices, however, have high failure, injury, and complication rates, requiring frequent revision surgeries. (*Id.* at ¶ 14). These failures stem from a variety of product design issues, including the material used in the devices and the required placement of the devices in a woman's pelvis. (*Id.*). Coonan alleges that "[f]easible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter." (*Id.* at ¶ 23). Coonan alleges that the defendants, in fact, "had already began using the safer alternatives in their other mesh products." (*Id.* at ¶ 55).

The defendants represented to Coonan and her physicians "through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions" that their pelvic mesh products were safe, safer than other alternative

devices, and more effective than other alternative devices. (*Id.* at ¶ 80). Moreover, the defendants "specifically promoted" the devices as producing minimal local tissue reactions, minimal tissue trauma, and minimal pain. (*Id.* at ¶ 9). Coonan alleges that she relied on these representations in deciding to be implanted with the devices. (*Id.* at ¶¶ 81, 83). Coonan also alleges that the defendants fraudulently withheld information concerning risks associated with the devices. (*Id.* at ¶¶ 80, 94). Coonan brings her claims under Massachusetts law. (Pl. Mem. at 2).

The defendants move to dismiss four of Coonan's six claims, arguing that Coonan has not pled sufficient facts that could plausibly show that she is entitled to relief. The Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a).

Discussion

In evaluating a Rule 12(b)(6) motion to dismiss, the Court must determine "whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintiff[], the complaint states a claim for which relief can be granted." *Cortés-Ramos v. Martin-Morales*, 956 F.3d 36, 41 (1st Cir. 2020) (quoting *Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 7 (1st Cir. 2011). The complaint must allege "a plausible entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 679.

Count I (Negligence)

The defendants argue that Count I should be dismissed because it is duplicative of other counts in the complaint. *See Engren v. Johnson & Johnson, Inc.*, 2021 WL 4255296, at *4 (D. Mass. Sept. 17, 2021). Count I, entitled "Negligence," alleges that the defendants had "a duty to

exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of their pelvic mesh products," and that the defendants breached that duty. (Am. Compl. at ¶¶ 41, 43). As clarified at the hearing on this motion, Coonan's negligence claim is based on theories of design defect and failure to warn.

Count II, entitled "Products Liability - Design Defect," alleges that the defendants' products were defectively designed. (*Id.* at ¶ 55). While Count II does not use the word "negligence" or "duty," both parties, in their briefing on this motion, treat Count II as asserting a negligence claim. (*See* Pl. Mem. at 4-5; Defs. Mem. at 7). Count III, entitled "Products Liability - Failure to Warn," alleges that the defendants were negligent in failing to warn Coonan of adverse reactions associated with the devices. (Am. Compl. at ¶ 62). Count V, entitled "Breach of Implied Warranty," alleges a breach of the implied warranty of merchantability under M. G. L. c. 106 § 2-314. (Am. Compl. at ¶¶ 90, 94). Count V specifically mentions failure to warn, (*Id.* at ¶ 98), but not design defect.

Products liability in Massachusetts may be premised on negligence or breach of warranty. In Massachusetts, "there is no 'strict liability in tort' apart from liability for breach of warranty under the Uniform Commercial Code," M. G. L. c. 106, § 2-314. *Swartz v. General Motors Corp.*, 378 N.E.2d 61, 63 (Mass. 1978). Only one of Coonan's claims, Count V, is brought under M. G. L. c. 106, § 2-314. That leaves three purported negligence claims (Counts I, II, and III) based on two theories of negligence (design defect and failure to warn). One claim must be duplicative.

To the extent Count I alleges failure-to-warn negligence, it is duplicative of Count III, which clearly alleges failure-to-warn negligence. To the extent Count I alleges negligent design, it may be duplicative of Count II, which the parties treat as asserting a negligent design claim. Because Count II does not specifically mention negligence, however, the Court cannot be sure that

Counts I and II are duplicative. Nonetheless, as discussed next, Coonan has not properly alleged a design defect claim. Thus, even if it is not duplicative, dismissal of Count I is warranted.

Count II (Products Liability - Design Defect)

The defendants argue that Count II should be dismissed because Coonan has not sufficiently pled a design defect claim; they assert that her allegations lack sufficient detail concerning how the devices are defective, how the defects caused her injuries, and whether a safer alternative design exists. To prevail on this claim, Coonan must show, *inter alia*, that the devices were defectively designed, which depends in part on the existence of a safer alternative design, and causation. *See Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1020-21, 1024 (Mass. 2013).

First, Coonan has sufficiently alleged defects in the devices' design. For example, she alleges that there are "biomechanical issues with the design of the mesh that can create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade and the device to migrate into organs and surrounding structures." (Am. Compl. at ¶ 14d). She also alleges that the "design of the arms" of the devices, even when placed correctly in the body, "are likely to pass through and injure major nerve routes in the pelvic region." (*Id.* at ¶ 14f). *See Back v. Wickes Corp.*, 378 N.E.2d 964, 970 (Mass. 1978) (among the factors relevant to a design defect are the gravity and likelihood of danger posed by the challenged design).

Second, Coonan has alleged sufficient facts to suggest that the design of the devices caused her injuries. Taking an example from the complaint just mentioned, Coonan alleges that the design of the devices causes the devices to degrade and migrate into organs and surrounding structures. (Am. Compl. at ¶ 14d). Coonan further alleges that she was required to undergo three surgeries to remove portions of the devices that had eroded into her vagina and bladder. (*Id.* at ¶¶ 36-38). Coonan's allegations are more detailed, and more specific to her, than the allegations in the cases

on which the defendants rely. *See Green v. Covidien LP*, 2021 WL 1198833, at *5 (S.D.N.Y. Mar. 30, 2021); *Dolan v. Boston Sci. Corp*, 2021 WL 69877, at *2 (D. Minn. Feb. 23, 2021); *Krulewich v. Covidien*, LP, 498 F. Supp. 3d 566, 576 (S.D.N.Y 2020); *Scism v. Ethicon, Inc.*, 2020 WL 1245349, at *4 (N.D.N.Y. Mar. 16, 2020). The complaint plausibly alleges causation.

Third, however, Coonan has not alleged sufficient facts to suggest the existence of a feasible alternative design. To prevail on a design defect claim, a plaintiff must show the existence of an available, safer design. See *Evans*, 990 N.E.2d at 1024-25. Coonan has alleged in conclusory fashion only that an alternative design exists and is used by the defendants in other devices. *Cf. Engren*, 2021 WL 4255296, at *3 (concluding that complaint sufficiently alleged a design defect where specific alternatives were listed). "Simply asserting that a feasible alternative design exists -- without pleading any supporting facts -- is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be." *Green v. Covidien LP*, 2019 WL 4142480, at *3 (S.D.N.Y. Aug. 30, 2019). Coonan's reliance on *Osorio v. One World Technologies Inc.*, 659 F.3d 81, 87 (1st Cir. 2011) is unavailing. That case was decided before *Evans*, 990 N.E.2d at 1024-25, where the Massachusetts Supreme Judicial Court held that the existence of a design defect depends on the existence of a feasible alternative design. *See Ducat v. Ethicon, Inc.*, 2021 WL 1408120, at *3-5 (D. Mass. Apr. 14, 2021). Accordingly, Count II is dismissed without prejudice and with leave to amend.[1]

Count IV (Breach of Express Warranty)

The defendants argue that Count IV should be dismissed because Coonan has not properly pled a breach of express warranty claim. "Under Massachusetts law, as elsewhere, an express

[1] Coonan should clarify in her amended complaint whether Count II is asserting a negligence theory of liability.

warranty in a contract is a promise of a particular standard of performance, and it imposes on the warrantor an obligation to fulfill the promise made." *Sparks v. Fidelity Nat. Title Ins. Co.*, 294 F.3d 259, 272 (1st Cir. 2002). "Advertisements can be express warranties under Massachusetts law." *Hebert v. Vantage Travel Service, Inc.*, 444 F. Supp. 3d 233, 245 (D. Mass. 2020). To establish a breach of warranty claim, the Coonan must "prove that statements or representations made by the seller induced [her] to purchase the good and that [she] relied on those statements or representations." *LePage v. E-One, Inc.*, 4 F. Supp. 3d 298, 312-13 (D. Mass. 2014).

Coonan alleges that the defendants specifically promoted the devices to physicians and patients "as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain." (Am. Compl. at ¶ 9). This alleged affirmation, unlike the affirmations alleged in the cases cited by the defendants, is specific as to what the defendants promised -- minimal tissue reactions and trauma and minimal pain. *Cf. Bustamante v. Atrium Medical Corp.*, 2020 WL 583745, at *9 (S.D.N.Y. Feb. 6, 2020) (claim dismissed where alleged affirmation was that product was "safe, effective, and adequately tested"); *Krulewich*, 498 F. Supp. 3d at 578-79 (claim dismissed where alleged affirmation was that product was safe and effective). Moreover, it is certainly plausible that Coonan and her doctor relied on these statements; according to the complaint, Coonan's doctor recommended that she be implanted with the TVT-Secur and Prolift devices specifically. (Am Compl. at ¶ 34). *See Engren*, 2021 WL 4255296, at *4. The defendants' motion with respect to Count IV is denied.

Count VI (Discovery Rule and Fraudulent Concealment)

The defendants argue that Count VI should be dismissed because the discovery rule is not a separate cause of action recognized under Massachusetts law. Count VI, entitled "Discovery Rule and Fraudulent Concealment," states that the Coonan "pleads that the discovery rule should

be applied to toll the running of the statute of limitations," and that the defendants are "estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between the injuries and Defendants' tortious conduct." (Am. Compl. at ¶¶ 102, 104).

The doctrine of fraudulent concealment operates to toll to the statute of limitations, *see Abdallah v. Bain Capital LLC*, 752 F.3d 114, 119-20 (1st Cir. 2014), but does not provide an independent cause of action, *see Epstein v. C.R. Bard, Inc.*, 460 F.3d 183, 189 n.4 (1st Cir. 2006) (plaintiff "erroneously pled fraudulent concealment as a separate cause of action"); *Harry v. Countrywide Home Loans Inc.*, 219 F. Supp. 3d 228, 235 (D. Mass. 2016). Accordingly, Count VI does not itself entitle Coonan to relief and, for that reason, is dismissed. Dismissal of Count VI, however, does not preclude Coonan from arguing that the statute of limitations is tolled by the doctrine of fraudulent concealment.

Conclusion

For the foregoing reasons, the defendants' motion is ***granted*** as to Counts I, II, and VI and ***denied*** as to Count IV. Coonan is granted leave to amend her complaint with respect to Count II. *See* Fed. R. Civ. P. 15(a)(2).

SO ORDERED

/s/ Timothy S. Hillman
TIMOTHY S. HILLMAN
DISTRICT JUDGE